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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,840	11/06/2001	Michael E. Jeffers	15966-557A (Cura 57A)	7261
55111 7590 08/17/2007 MINTZ, LEVIN, COHN, FERRIS, GLOVSKY & POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			EXAMINER SEHARASEYON, JEGATHEESAN	
			ART UNIT	PAPER NUMBER
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			08/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/992,840	Applicant(s) JEFFERS ET AL.	
	Examiner Jegatheesan Seharaseyon, Ph.D	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6-8,11-19,22-30 and 33-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-8,11-19,22-30 and 33-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Amd. cover sheet</u> . |

DETAILED ACTION

1. This Office Action is in response Applicant's remarks and amendment filed 6/4/2007. Claims 4, 5, 9-10, 20, 21, 31, 32, 44 and 45 have been cancelled. Claims 1, 6, 17, 28 and 39 have been amended. Thus, claims 1, 2, 3, 6-8, 11—19, 22-30 and 33-43 are pending and under consideration in this action.

2. Applicant has amended the title to better reflect the invention.

3. Applicant has amended the specification to update the priority information and corrected the typographical errors.

4. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn.

5. The Office inadvertently did not include Claim 39 and its dependent claims in the 112, 2nd rejections.

Claim Rejections - 35 USC § 112, second paragraph, maintained

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6a. The rejection of claims 1, 6, 17, 28 and 39 as being vague and indefinite in the recitation of the term "FCTR" is maintained. As indicated in the Office Action dated 3/2/2007, abbreviations and acronyms should be spelled out at their first use in the claims for clarity. The protein of interest is described by an arbitrary abbreviation. Claims 2, 3, 7, 8, 11-16, 18, 19, 22-27, 29, 33-38 and 40-43 are rejected insofar as they depend on rejected claims 1, 6, 17, 28 and 39.

Claim Rejections - 35 USC § 112, first paragraph, maintained

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7a. The rejection of claims 1, 2, 3, 6, 7, 8, 11-19, 22-30 and 33- 43 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons of record in the Office Action dated 3/2/07 (pages 4-7). Specifically, claims 1,6, 17, 28 and 39 as amended recite the phrases “a deletion mutant of the amino acid sequence of SEQ ID NO: 2” and “C-terminal fragments thereof having an apparent molecular weight of approximately 35 kDa” and thus, are broadly interpreted by the Examiner as reading upon: (i) all polypeptide deletion mutants of SEQ ID NO: 2 and (ii) all C-terminal fragments having an apparent molecular weight of approximately 35 kDa .

Applicant claims that the polypeptides are described throughout the specification as originally filed, e-g., in Tables 1-7, in Examples 10-11 and in Examples 10-11 and in Example 21. Thus, it is asserted that disclosure provided is commensurate with the scope of the amended claims. Applicant's arguments have been fully considered but not found to be persuasive.

While the specification provides written description support for deletion mutants that have residues 54-64 or residues 24-211 of SEQ ID NO: 2 (see pages 114-115), it

does not provide written description support for all deletion mutants of SEQ ID NO: 2. Similarly, the specification discloses the C-terminal fragment of FCTR_X (PDGFD or 30664188.0.99) with an apparent molecular weight of 35kDa (page 121-123). There is no written description support for all C-terminal fragments having an apparent molecular weight of approximately 35 kDa. The specification does not provide written description to support the genus encompassed by the instant claims. Therefore, the skilled artisan cannot envision all the detailed chemical structure of the claimed polypeptide sequences of the variant polypeptides regardless of the complexity or simplicity of the method of isolation. Therefore, the rejection of record is maintained.

7b. The rejection of claims 1, 2, 3, 6, 7, 8, 11-19, 22-30 and 33- 43 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for for deletion mutants that have residues 54-64 or residues 24-211 of SEQ ID NO: 2 (see pages 114-115) and the C-terminal fragment of FCTR_X (PDGFD or 30664188.0.99) with an apparent molecular weight of 35kDa (page 121-123), does not reasonably provide enablement for all deletion mutants of SEQ ID NO: 2 and for all C-terminal fragments having an apparent molecular weight of approximately 35 kDa is maintained for reasons of record in the Office Action dated 3/2/07 (pages 7-12). Specifically, claims 1,6, 17, 28 and 39 as amended recite the phrases “a deletion mutant of the amino acid sequence of SEQ ID NO: 2” and “C-terminal fragments thereof having an apparent molecular weight of approximately 35 kDa” and thus, are broadly interpreted by the Examiner as reading upon: (i) all polypeptide deletion mutants of SEQ ID NO: 2 and (ii) all C-terminal fragments having an apparent molecular weight of approximately 35 kDa .

Applicant argues that the specification provides ample guidance so as to be enabling for the claimed FGF-CX and FCTR-X-polypeptide, and undue experimentation would not be required to identify which polypeptides are encompassed by the scope of the amended claims. Applicant's arguments have been fully considered but not found to be persuasive.

While the specification provides enabling disclosure for deletion mutants that have residues 54-64 or residues 24-211 of SEQ ID NO: 2 (see pages 114-115), it does not provide enablement support for all deletion mutants of SEQ ID NO: 2. Similarly, the specification provides enabling disclosure for the C-terminal fragment of FCTR-X (PDGFD or 30664188.0.99) with an apparent molecular weight of 35kDa (page 121-123). However, there is no enabling disclosure for all C-terminal fragments having an apparent molecular weight of approximately 35 kDa. It would require undue experimentation to identify all the deletion mutants of SEQ ID NO: 2 and C-terminal fragments of FCTR-X with an apparent molecular weight of 35kDa that also contain the functional attributes of the instant invention. For example, there is no guidance provided in the specification with respect to the minimal polypeptide required for growth promotion or treating an inflammatory pathology. Therefore, the rejection of record is maintained.

Double Patenting, maintained

8. The obvious-type double patenting rejection of claims 6-8, 11-16 and 28-30, 33-36 over claims 1-9 and 11-26 of U.S. Patent No. 6, 982, 250 and claims 1-3, 6-8, 11-19, 22-30 and 33-38 over claims 1-3, 5-8, 19, 21-30 and 32-38 of co-pending

Art Unit: 1647

Application No. 10/321, 962 (Now U. S. Patent No. 7, 189, 693) is maintained for reasons set forth in the Office Action dated 3/2/07 (pages 18-20). Although, Applicant indicates that there is a terminal disclaimer for '250 patent and '693 patent, there is none (see Amdt. cover sheet enclosed). The rejection will be withdrawn upon Applicant providing the appropriate terminal disclaimers.

9. No claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao, Ph. D can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

Application/Control Number: 09/992,840

Page 7

Art Unit: 1647

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS

Art Unit 1647

August 15th, 2007

Gegatheesu Selva Jay
Patent Examiner